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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/853,880	05/14/2001	Gregory J. Riggins	00250.00003	6566

22907 7590 10/07/2003

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EXAMINER

YAEN, CHRISTOPHER H

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 10/07/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/853,880

Applicant(s)

RIGGINS ET AL.

Examiner

Christopher H Yaen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13, 16 and 18-47 is/are pending in the application.
- 4a) Of the above claim(s) 1-12 and 23-47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13, 16 and 18-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. The amendment filed 7/15/2003 (paper no. 12) is acknowledged and entered into the record. Accordingly, claims 14-15, and 17 are canceled without prejudice or disclaimer. Claims 1-13, 16, 18-47 are pending, claims 1-12, and 23-47 are withdrawn from further consideration as being drawn to a non-elected invention.

2. This application contains claims 1-12 and 23-47 drawn to an invention nonelected in Paper No. 9. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

3. Therefore, claims 13,16, and 18-22 are examined on the merits.

Claim Rejections Maintained - 35 USC § 112, 1st paragraph

4. The rejection of claims 13, 16, and 18-22 under 35 USC 112, 1st paragraph as lacking enablement is maintained for the reasons of record. Applicant argues that the specification provides adequate disclosure so as to enable the skilled artisan. Applicant argues several points made in the prior office action. First, applicant states that the specification provides information on the protein termed GPNMB and that the protein is disclosed by accession number. Second, applicant argues that the specification provides teachings that the protein in fact does exist because antibodies that are specific for the protein are used through out the specification (see page 5 paper no. 12). Next, the applicant argues that the examiner makes speculative arguments to assert that the protein termed GPNMB does not exists and that such assertions are not supported by the law. Applicant argues that statements made in the specification must

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be presumed as the truth unless there is objective evidence that such statements are false. And lastly, applicant argues that the examiner has not examined the specification as a whole and has limited the applicant to the scope of the working examples.

The applicant's arguments have been carefully considered but are not found persuasive. First, it appears that the protein, GPNMP is essential material needed for the practice of the instant invention. The specification has defined GPNMP by a GenBank Accession number, of which are incorporated by reference (see page 26). Such incorporation is not seen as sufficient so as to enable the skilled artisan to make the instant invention commensurate in scope to what is claimed. Furthermore, the accession numbers are an ever evolving number system that changes upon corrections to the sequence. As such the skilled artisan is unable to adequately practice the invention without knowing the sequence to the claimed GPNMP. The incorporation of essential material in the specification by reference to a foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by the applicant, or a practitioner representing the applicant, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. See *In re Hawkins*, 486 F.2d 569, 179 USPQ 157 (CCPA 1973); *In re Hawkins*, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); and *In re Hawkins*, 486 F.2d 577, 179 USPQ 167 (CCPA 1973).

Secondly, the specification has only disclosed prophetic embodiments of how to use an antibody for the detection of a specific antigen. The specification has not

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actually taught the identification or characterization of GPNMB (aside GenBank Accession number), its expression pattern in cancerous versus normal cells, and how the targeting of a cytotoxic conjugate linked to a GPNMB specific antibody is to be effective if administered. Therapeutic agents may be inactivated *in vivo* before producing a therapeutic effect, for example, by proteolytic degradation, immunological activation or due to an inherently short half life. In addition, the therapeutic agent may not otherwise reach the target because it may be absorbed by fluids, cells and tissues where the therapeutic agent has no effect, circulation into the target area may be insufficient to carry the therapeutic agent and a large enough local concentration may not be established. The specification provides insufficient guidance with regard to these issues and provides no working examples which would provide guidance to one skilled in the art and no evidence has been provided which would allow one of skill in the art to predict the efficacy of the claimed therapeutic agent with a reasonable expectation of success. For the above reasons, it appears that undue experimentation would be required to practice the claimed inventions with a reasonable expectation of success.

Because of the lack of supportive evidence provided by the specification with regard to the identity of the claimed protein, its expression pattern, its localization, and its actual existence, the statements regarding the existence of the GPNMB is not at all speculation based without merit. The specification identifies the protein by GenBank Accession number. The specification does not go into any other detail except for mRNA expression data. No comparisons have been made between normal cells and cancerous cells with regard to the expression of GPNMB so as to be a cancer specific

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target for the conjugate. No experimental data exists for any antibody that has recognized the GPNMB, the ability to localize to the target or the effects of such targeting. Therefore, no definitive statements have been made concerning the expression, localization, or the nature of GPNMB, except for the Genbank Accession number, and as such, methods for specifically delivering a reagent to a glioblastoma has not been taught and as such the skilled artisan would not be able to practice the invention commensurate in scope to the claims. Although it is true that the scope of the invention is not to be limited by the working examples, however, in this case because the working examples are broad descriptions of using antibodies or dendritic vaccines regimens for the treatment of cancer, it does not teach one of skill how to use, the instant invention in terms of how to monitor and determine the effectiveness of the targeting conjugate. Typically the working examples provide experimental data of desired embodiments found in the detailed specification. However, because the instant specification lacks any descriptive detail in terms of what the GPNMB protein does, is or its expression pattern on cancerous versus non-cancerous cells, the working example should demonstrate to one of skill how to use the claimed embodiments of the invention.

All other rejections and or objections are withdrawn in view of the applicant's amendments and arguments thereto as set forth in Paper No. 12.

Conclusion

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5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 703-305-3586. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



ANTHONY C. CAPUTA
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Christopher Yaen
Art Unit 1642
October 2, 2003